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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,935

Applicant(s)

STAUNTON, DONALD E.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,9,18,19,22-25,30-32,36-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,10-17,20,21,26-29,33-35 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This Office action is non-final because it contains a new grounds of rejection under 35 U.S.C. 102(b) not necessitated by the applicant's amendment.

Election/Restrictions

2. After entry of the amendment filed 28 March 2005, claims 6, 8, 9, 18, 19, 22, 23, 24, 25, 30-32, 36-47, and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Specification

3. The objection to the specification in the Office action mailed 24 September 2004 is withdrawn in view of the amendment to the specification and new sequence listing filed 28 March 2005.

Claim Objections

4. The objection to claim 23 in the Office action mailed 24 September 2004 is withdrawn in view of the amendment to the claim filed 28 March 2005.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5, 7, 10-17, 20, 21, 26-29, 33-35, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of contacting a protein containing alpha helices and beta sheet structures with an effector that interacts with an allosteric regulatory site of the protein and modulates binding of the protein with a ligand. In some embodiments the protein is broadly claimed as a molecule that is not LFA-1 or an I domain containing fragment thereof. In some embodiments the protein is more narrowly claimed as having less than 40% similarity to LFA-1. In some embodiments the protein is limited to the elected species of FtsZ and the ligand is GTP. In some embodiments the effector is a diaryl compound or a diaryl sulfide compound. In some embodiments the protein comprises a Rossmann fold with a 321456, 321456, or 231456 beta sheet structure. In some embodiments the effector increases binding of the ligand and increases enzymatic activity of the protein. In some embodiments the effector decreases binding of the ligand and decreases enzymatic activity of the protein. It is emphasized that the generic claims are drawn broadly to all proteins that are not excluded. The claims read on both in vitro and in vivo methods.

The specification describes in Table 1 on pages 30-66 lists 96 classes of proteins with alpha beta structures. The specification describes working examples of ? first molecules as claimed:

- 1) CD11B in example 3, pages 87-89 and example 16, pages 127-128
- 2 and 3) C2 and factor B in example 4, pages 89-96
- 4-11) seven integrins in example 9, pages 107-111 (see Table 5, page 111)
- 12-13) two integrins in example 11, pages 114-116

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14) alpha 1 integrin in example 12, pages 116-122

15) Rac 1 in example 17, pages 128-131

16) ENR in example 21, pages 143-145

17) HPPK in example 19, pages 133-141.

In considering the broad scope of the generic claims the 17 species of first molecules described do not adequately describe the generic claims. The broadest claim reads on methods utilizing all proteins that comprise alpha helix and beta sheet secondary structures except one protein, LFA-1. Description of methods using 17 proteins in the specification does not comprise a representative number of the undefined large genus of claimed methods.

Regarding the elected species of a method of using FtsZ, the specification shows in example 20 on pages 142-143 a prophetic example of a FtsZ binding assay, and describes FtsZ on page 19 and lists FtsZ in table 3 on page 84. However the specification does not describe an allosteric site in FtsZ, or effectors of any type of FtsZ. The specification does not describe the Rossmann fold structure of FtsZ. It is noted that claims 35 and 48 have been examined and not withdrawn although the specification does not show in Table 1 the elected species of protein FtsZ as required in claims 35 and 48. The specification does not describe a method utilizing FtsZ that comprises effectors, or the claimed structural limitations of FtsZ such as Rossmann folds, or the claimed structural and functional limitations of the effector on FtsZ such as increasing or decreasing binding or enzymatic activity and diaryl structures. In addition to the lack of description discussed in the preceding paragraph of the generic claims, the specification fails to describe the elected method.

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7. Applicant's arguments filed 28 March 2005 have been fully considered but they are not persuasive. The applicants point to additional examples of first molecules in the examples section of the specification. The rejection detailed above has been modified to increase the number of working examples of first molecules from 9 to 17. However the extent of working examples still does not sufficiently describe the genus of claimed first molecules, which includes all molecules that are not LFA-1. In addition the applicants point to Examples 15, 18, 19, and 20 for support of written description, however Examples 15, 18, 19, and 20 do not provide results that support the claimed method. In particular Example 20 does not provide results that describe the elected FtsZ species.

8. The rejection of claims 26-29 in the Office action mailed 24 September 2004 is withdrawn in view of the amendment to the claims filed 28 March 2005.

Claim Rejections - 35 USC § 102

9. The rejection of claims 1, 4, 5, 7, 10, 13-17, 20, 21, 26, 27, 33-35, and 48 are rejected under 35 U.S.C. 102(b) as being anticipate by Yu et al. (reference C59 in the Information Disclosure Statement filed 26 August 2002 as evidenced by Nogales et al. in the Office action mailed 24 September 2004 is withdrawn in view of the arguments presented by the applicants on page 16 of the response filed 28 March 2005.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 1, 4, 10, 13, 14, 15, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Collier as evidenced by Hynes.

The claims are drawn to a method of contacting an integrin protein with an effector that interacts with an allosteric regulatory site and modulates binding of the protein with a ligand. In some embodiments the protein comprises a Rossmann fold beta sheet structure. In some embodiments the effector decreases binding of the ligand.

Collier shows a monoclonal antibody fragment antagonist of an integrin, namely GPIIb/IIIa that is involved in platelet aggregation. The antibody fragment has been licensed for treatment of ischemic complications after angioplasty. Collier discusses high and low affinity conformations of GPIIb/IIIa on pages 1467-1468. Collier also discusses antagonists of $\alpha_v\beta_3$ integrin molecules on page 1469.

Hynes reviews integrins and shows that their structure comprises Rossmann fold beta sheets on page 676.

Conclusion

12. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

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problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 10 May 2005
John S. Brusca
Primary Examiner
Art Unit 1631

jsb